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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/039,383

12/17/2001

Hsien-Juc Chu

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05/23/2006

EXAMINER

DEVI, SARVAMANGALA J N

WYETH
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5 GIRALDA FARMS
MADISON, NJ 07940

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/039,383	CHU ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Attachment.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: None.
- Claim(s) objected to: None.
- Claim(s) rejected: 10-12 and 14-17.
- Claim(s) withdrawn from consideration: None.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: Attachment.

ATTACHMENT TO ADVISORY ACTION

Applicants' After-final Amendment

- 1) Acknowledgment is made of Applicants' after-final amendment filed 05/10/06 in response to the final Office Action mailed 03/09/06.

Status of Claims

- 2) Claim 17 has been amended via the amendment filed 05/10/06.
Claims 10-12 and 14-17 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Terminal Disclaimer

- 5) Acknowledgment is made of Applicants' terminal disclaimer filed 05/10/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 7,018,638 issued from application 10/150,597.

Objection Withdrawn

- 6) The objection to the improperly multiple dependent claim 17 in paragraph 14 of the Office Action mailed 03/09/06 is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Withdrawn

- 7) The provisional rejection of claims 10-12 and 14-17 made in paragraph 10 of the Office Action mailed 09/07/05 and maintained in paragraph 12 of the Office Action mailed 03/09/06 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-18 of the co-pending application, SN 10/150,597, is withdrawn in light of Applicants' submission of a terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 7,018,638 issued from application 10/150,597.

Rejection(s) Maintained

8) The rejection of claim 10 and those dependent therefrom made in paragraph 13 of the Office Action mailed 03/09/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

Applicants contend that with the exception of the phrase "or disease," the claim language of claim 10 was 'substantially copied' from the proposed Examiner's amendment sent to the attorney of record by facsimile in August 2005. Applicants explain how the limitation 'or disease' is supported in the specification. Applicants assert that the recitation 'said' used with some terms have proper antecedent basis in the claim. Applicants discuss of the Office's alleged belief that the previous amendment contained new matter by omitting a step from the method by not claiming an age limitation ('at the age of three weeks'). Applicants assert that the step is not taught as critical in the examples. In response to the new matter rejection made under 35 U.S.C. § 112, first paragraph, Applicants discuss the 'unexpected results' demonstrated in the working examples, and the 'surprising' showing in the instant invention that the new one-dose unique formulation is superior to the art-existing SUVAXAN RESPIFEND MH. Applicants assert that: (a) This showing is relevant to the adjuvant system and has absolutely nothing to do with the age of the piglet; (b) The pig's age is not crucial to the practice of the present invention; (c) The age restriction is not warranted under the circumstances; (d) The administration of the recited vaccine in the field will vary somewhat from an exact three weeks from date of birth and that is more of a question of maturity than a precise age; (e) The dosing schedule will depend upon the maturity of the immune system and the weakening or depletion of the maternal antibodies in the pig being immunized; (f) The pig farmer may not know the precise age of all the piglets on the farm or be able to immunize all piglets at the same age of three weeks old; (g) The specification illustrates vaccinating the piglets at three weeks old; (h) It is desirable to administer the vaccine to the piglets at an early age to avoid *M. hyopneumoniae* infection or disease and the exact timing of the administration of the vaccine is not always at three weeks after birth; (i) Vaccination protocol will follow what is customary in the usage and trade of the swine business; and (j) The ordinary practitioner will know when it is the right time and the right age to vaccinate the piglets to achieve successful results.

Applicants' arguments have been carefully considered, but are not persuasive. First, contrary to Applicants' assertion, claim 10 as amended via Applicants' amendment filed

12/07/05, is not a substantial copy of claim 10 that was proposed to Applicants in August 2005 as one can make out from the copy of the proposed claim supplied by Applicants. Clearly, claim 10 as amended by Applicants does not copy the limitation --at the age of three weeks--. Secondly, this omitted age limitation does not constitute a method step as stated by Applicants, but the age of the recited porcine animal in which protective immunity is elicited against *Mycoplasma hyopneumoniae* infection specifically for a duration of six months after the single administration of the recited vaccine composition. As set forth previously, with the exclusion of this age limitation from the claim, the claimed method would have a different and new broader scope, for which there is no support in the instant specification, as originally filed. Applicants did not have possession of the method claimed in claim 10 as amended via Applicants' amendment filed 12/07/05. As set forth previously, the instant specification documents that the protective immunity against *Mycoplasma hyopneumoniae* infection or disease (as measured by lung lesion scores) elicited by the vaccine recited in claim 10 after a single administration, the duration of which immunity lasted specifically for a duration of six months, is limited to porcine animals that were administered said single dose --at the age of three weeks--. See instant specification at lines 3-6 of page 20; lines 3-11 and 14-23 of page 21; lines 1-14 on page 22; lines 19-27 of page 23; Table 5; and the last four lines on page 25. The method of protecting a porcine animal of any age by administering the recited vaccine and eliciting protective immunity against *Mycoplasma hyopneumoniae* infection or disease for a duration of six months following a single administration is not supported in the instant specification.

With regard to Applicants' remarks on the 'unexpected results' and the 'surprising' showings within the specification, Applicants are reminded that the rejection of record is not an obviousness rejection made under 35 U.S.C. § 103. Obviousness is not the standard for the addition of new limitations to the disclosure or deletion of limitations from the claims that changes the scope of the claimed invention. The specification as filed does not sufficiently support the scope of the now claimed method, and therefore the amended claim 10 with its new scope introduces new concepts and violates the description requirement of the first paragraph of 35 U.S.C § 112.

Applicants are further reminded that *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1115 (CAFC 1991) makes clear that the written description provision of 35 U.S.C § 112 is severable from its enablement provision (see page 1115). Whether or not the pig farmer knows the precise

age of all the piglets, what vaccination protocol is customary in the usage and trade of the swine business, and whether or not an ordinary practitioner will know when is the right time and the right age to vaccinate the piglets to achieve successful results, are not the criteria that satisfy the written description provision of 35 U.S.C § 112 (new matter). The rejection is maintained for the reasons delineated above.


Remarks

- 9) Claims 10-12 and 14-17 stand rejected.
- 10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER